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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,801	01/26/2005	Naouki Yamamoto	04703/0202222-US0	1323
7278	7590	08/30/2007		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER AFREMOVA, VERA	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 08/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/518,801

Applicant(s)

YAMAMOTO ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9, 12 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 12 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/26/2005; 2/28/2005; 5/09/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of the species such as *Lactobacillus acidophilus* strain CL92 in the reply filed on 7/02/2007 as the species for the prosecution of the previously elected invention of the Group III (reply filed on 4/04/2007) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction/election requirement(s), the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 20 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to the nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 7/02/2007.

**Claims 9, 12 and 21 are under examination in the instant office action.**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 9-2959 (IDS reference) or by WO 01/37865 (IDS reference).

Claims are directed to a method for reducing allergy in a subject in need of such reduction wherein the method comprises administering to the subject an effective dose of an anti-allergic agent comprising lactic acid bacteria selected from the group consisting of *Lactobacillus*

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*acidophilus* and/or *Lactobacillus fermentum*. Some claims are further drawn to the use of lactic acid bacteria that are capable of reducing antigen-specific IgE level.

JP 9-2959 discloses a method for reducing allergy and lowering IgE levels by administering lactic acid bacteria that belong to the *Lactobacillus acidophilus* and/or *Lactobacillus fermentum* (see English abstract).

WO 01/37865 discloses a method for reducing allergy and lowering IgE levels by administering lactic acid bacteria that belong to the *Lactobacillus acidophilus* (entire document including abstract, page 2 at lines 5-15 and pages 8-9). WO 01/37865 teaches that the cells of *Lactobacillus acidophilus* are capable, when administered orally, to suppress antigen-specific IgE level in blood in a mouse rhinitis model wherein antigen-specific IgE level in blood has been elevated by nasally exposing the mouse to continuous antigen stimulation (pages 8-10).

Thus, each cited document JP 9-2959 or WO 01/37865 discloses identical method for reducing allergy and lowering IgE levels in subjects wherein the method comprises identical active step of administering identical lactic bacteria as required by the claimed method.

Therefore, each cited document JP 9-2959 or WO 01/37865 anticipates the claimed invention.

Claims 9, 12 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,516,684 (Saito et al).

Claims are directed to a method for reducing allergy in a subject in need of such reduction wherein the method comprises one active step of administering to the subject an effective dose of an anti-allergic agent comprising lactic acid bacteria selected from the group

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consisting of *Lactobacillus acidophilus*. Some claims are further drawn to the use of lactic acid bacteria that are capable of reducing antigen-specific IgE level. Some claims are further drawn to the use of lactic acid bacteria that belong to the *Lactobacillus acidophilus* strain CL92.

US 5,516,684 (Saito et al) discloses lactic acid bacteria that belong to the *Lactobacillus acidophilus* strain CL92 (FERM BP-4981) (page 3, lines 10-20) and teaches a method for treating a subject wherein the method comprises one active step of orally administering to the subject the cells of *Lactobacillus acidophilus* strain CL92 (FERM BP-4981) in amounts  $10 \times 4$  to  $10 \times 11$  cells per day (abstract and col. 5, lines 20-68). The cited method comprises one identical active step of administering identical bacterial cells and, thus, the effect of this treatment are reasonably expected to be the same effects including reducing allergy and lowering IgE level effects as the results of identical treatment. Moreover, the disclosed administration doses (col. 5, lines 55-60) are the same as intended for the claimed method (specification page 9, lines 1-10).

Therefore, the cited patent US 5,516,684 (Saito et al) anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 9-2959 and/or WO 01/37865 taken with US 5,516,684 (Saito et al).

Claims are directed to a method for reducing allergy in a subject in need of such reduction wherein the method comprises administering to the subject an effective dose of an anti-allergic agent comprising lactic acid bacteria selected from the group consisting of *Lactobacillus acidophilus* and/or *Lactobacillus fermentum*. Some claims are further drawn to the use of lactic acid bacteria that are capable of reducing antigen-specific IgE level. Some claims are further drawn to the use of lactic acid bacteria that belong to the *Lactobacillus acidophilus* strain CL92.

JP 9-2959 and WO 01/37865 disclose methods for reducing allergy and lowering IgE levels by administering lactic acid bacteria that belong to the *Lactobacillus acidophilus* and/or *Lactobacillus fermentum* as explained above. The lactic bacteria are generic bacteria belonging to the biological species of *Lactobacillus acidophilus* (WO 01/37865) and some particular strains belonging to the biological species of *Lactobacillus acidophilus* (JP 9-2959). But the cited JP 9-2959 and WO 01/37865 are lacking particular disclosure about the use of particular strain such as *Lactobacillus acidophilus* strain CL92.

However, the *Lactobacillus acidophilus* strain CL92 has been known and used for oral administration as a beneficial feed product as taught by US 5,516,684 (Saito et al).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the methods of JP 9-2959 and/or WO 01/37865 by administering cells *Lactobacillus acidophilus* strain CL92 as active ingredients with a reasonable expectation of success for reducing allergy and lowering IgE levels because cells belonging to the biological species *Lactobacillus acidophilus* have been known, used and/or suggested for reducing allergy and lowering IgE levels as adequately demonstrated by JP 9-2959 and/or WO 01/37865. Thus, substitution of *Lactobacillus acidophilus* strain CL92 for the other strains

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belonging to the biological species *Lactobacillus acidophilus* is considered to be substitution of equivalents. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

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August 27, 2007



VERA AFREMOVA

PRIMARY EXAMINER